July 2022

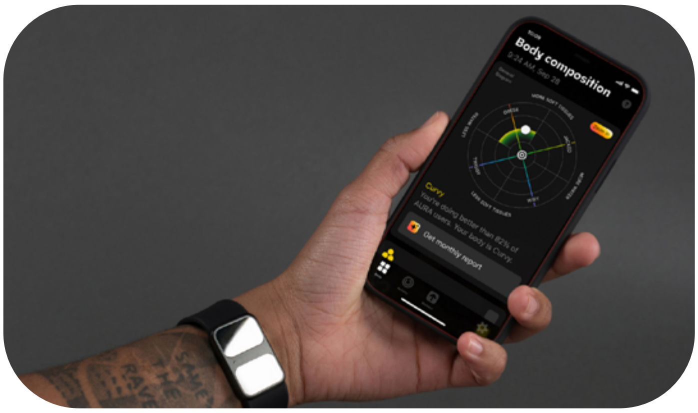
AURA Strap 2: Measurement Validation Research

Ensuring the precision of hand-to-hand BIA measurement

Introduction

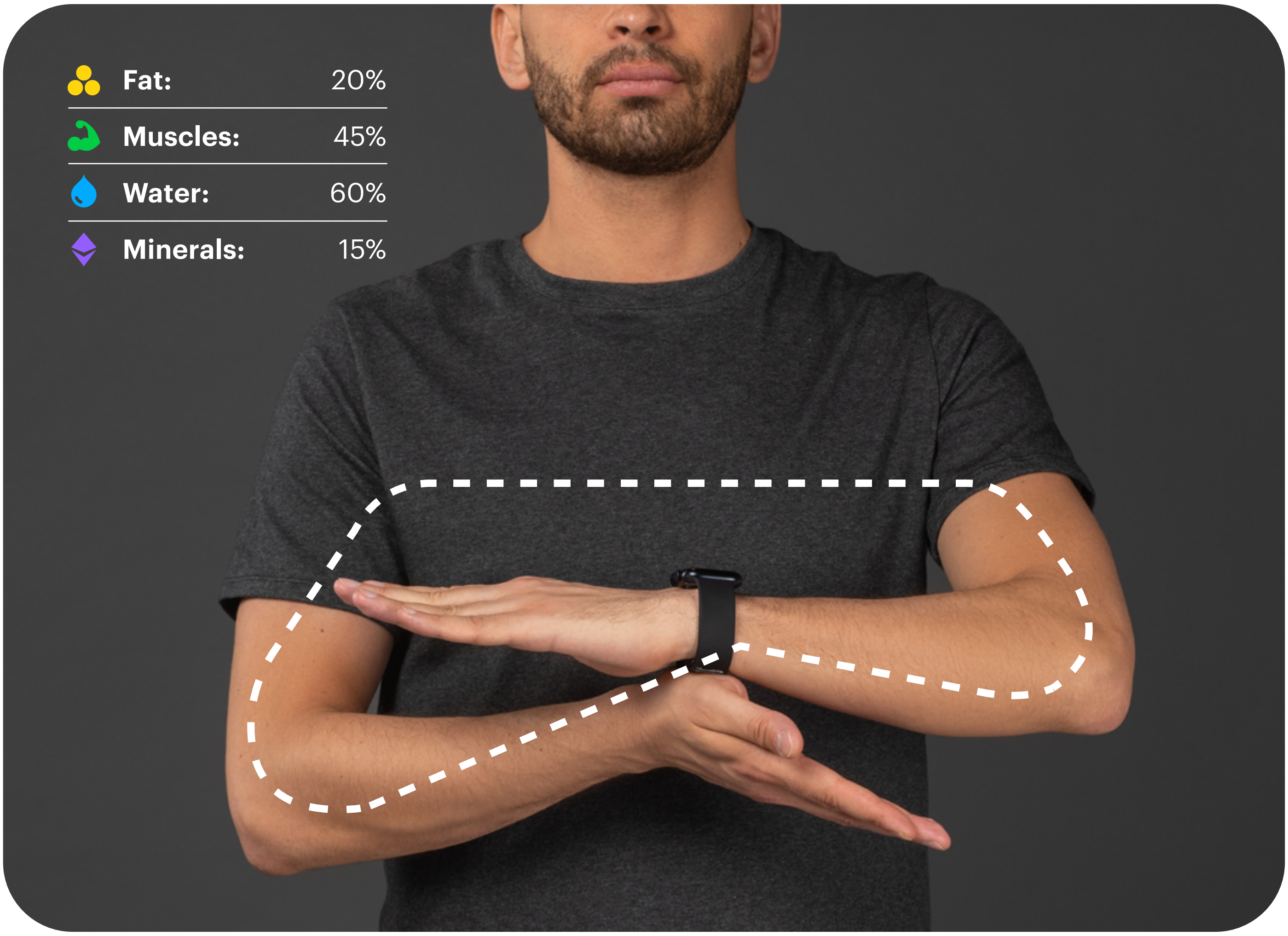
AURA Strap 2 is a wrist-wearable Apple Watch accessory that takes hand-to-hand bioelectrical impedance (BIA) measurements to provide the user with information about body composition and water level.

We at the AURA Devices R&D team conducted a study with the aim of building a novel non-empirical fat-free mass (FFM) estimation model based on anthropometric parameters and BIA values. We validated the model’s effectiveness against commercially available BIA devices and methods, including Lunar iDXA, inBody230, and Samsung Galaxy Watch 4.



What is bioelectrical impedance analysis (BIA)?

BIA is a widely used method for body composition evaluation since it is simple, quick, non-invasive, and inexpensive [1]. The BIA technique is based on measuring the impedance of different body pathways, which is determined by placing electrodes on different parts of the human body (the region of interest). In general, there is a strong correlation between measured values of bioimpedance and fat-free mass (body mass - fat mass) because of significant differences in tissues' electrical properties: the electrical conductivity of adipose tissue (or fat tissue) is much higher than that of muscle tissue [2]. This fact makes it possible to predict the mass of various components of the body using statistical methods.



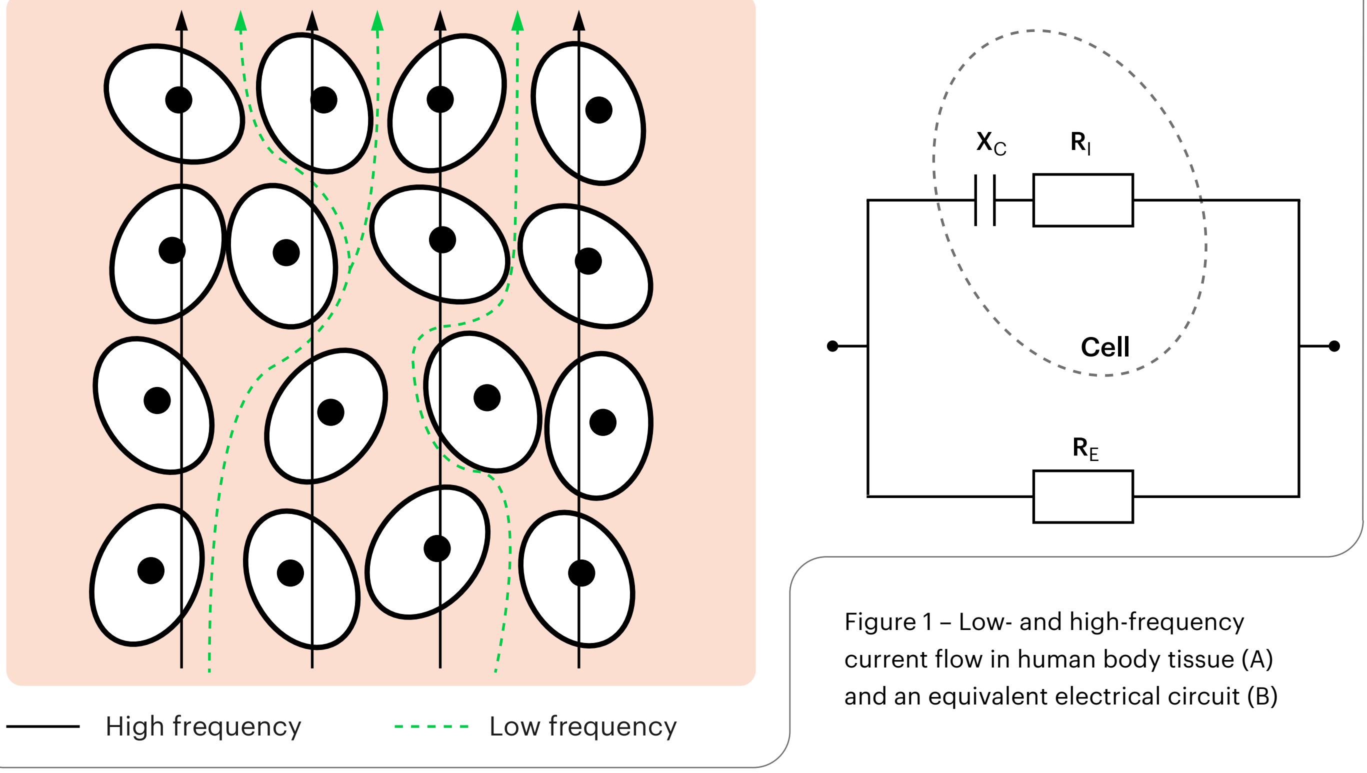


Figure 1 – Low- and high-frequency current flow in human body tissue (A) and an equivalent electrical circuit (B)

The physical method of the BIA technique is based on the following: since the human body consists of cells containing intracellular water (ICW) and organelles, and bathed in extra-cellular water (ECW), an alternating current (AC) sent through the body will experience a voltage drop (or potential difference) in water as an electrical conductor. At the same time, ECW- and ICW-separated cell membranes behave as a capacitor due to the very low conductivity of the membrane. (It can be considered as dielectric [3]) The electrical conductivity of this system is dependent on electrolyte concentration and the frequency of the applied current: low-frequency current passes through ECW and can’t penetrate the cell membrane since its reactance is too high ($X_c = 1 / 2\pi fC$), whereas high-frequency current passes through membranes and interacts with ICW as well (Figure 1A) [4].

The BIA technique measures impedance as an opposition to the alternating current flow. It is composed of resistance (R) and capacitive reactance (Xc) as a result of cell membrane opposition. In general, body tissue can be considered as a parallel electrical circuit with ECW as a resistor on one branch and ICW resistance and cell membrane capacitance on the other (Figure 1B) [5]. In practice, BIA devices measure the absolute value of bioimpedance and phase angle. Using those parameters, it is possible to calculate resistance and reactance.
For example, resistance is used to calculate the resistance index (H2/R, where H is the height of the person), which is roughly proportional to the total body water (TBW). Moreover, FFM is generally assumed to be a constant value of TBW: FFM = TBW x 0.73 [6]. Consequently, fat mass (FM) is simply calculated by the difference: FM = body mass - FFM.

The cornerstone of BIA is the predictive model. Depending on the purpose, the predictive model and BIA device configuration should be different. Usually, BIA models are formed by training multiple linear regressions, where DEXA (dual-energy X-ray absorptiometry) results are used as training data [7] (even though DEXA as an FFM estimation method does have its own bias). An example of this approach is the single cylinder-based BIA model, in which FFM is determined by the value of the resistance index. The model assumes the human body is an isotropic conductor with a constant cross-sectional area, with the length of the conductor being the height.

Although it is required to analyze only one pathway, this also makes it necessary to add age and sex variables to the prediction models in order to consider age and sex differences in fat and muscle mass body distribution among the population [8, 9]. However, as the human body has a more complex shape than a single cylinder, the model has severe limitations.

For accuracy purposes, the human body can be represented as five cylindrical conductors: four limbs and a torso, excluding the head.

With such a five-cylinder model, empirical estimation can be minimized due to direct impedance measurement of body parts [10]. The model's main drawback is the requirement of a multielectrode system (octapolar electrode system), contacting each limb, usually incorporated in a bulky full-size device, which is suitable for the laboratory, but not for home use.

Although laboratory BIA measuring equipment has multiple advantages such as higher accuracy and inter-observer reproducibility, interest in portable BIA devices, especially wearable ones, has been growing in recent years, mainly due to the growing wearable devices market [11].

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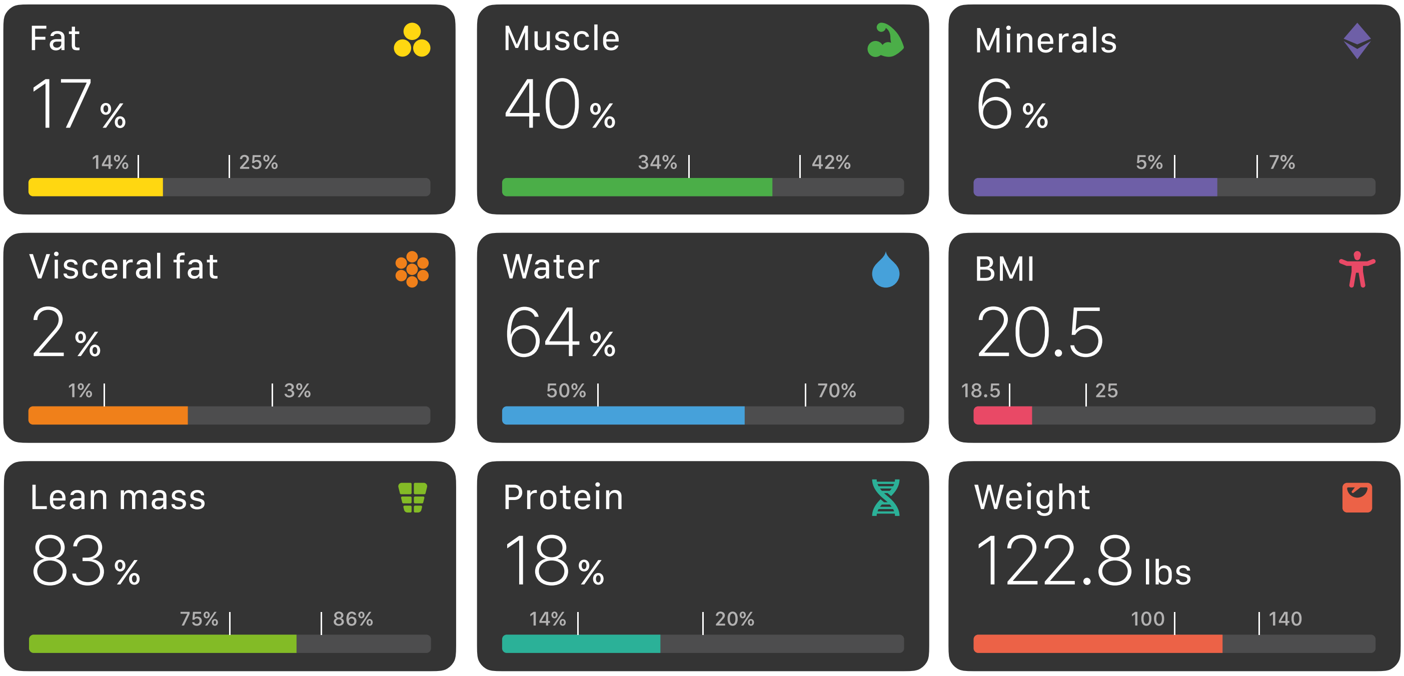
What is bioelectrical impedance analysis (BIA)?



Fat 17 % 14% 25%

Muscle 40 % 34% 42%

Minerals 6 % 5% 7%

Visceral fat 2 % 1% 3%

Water 64 % 50% 70%

BMI 20.5 18.5 25

Lean mass 83 % 75% 86%

Protein 18 % 14% 20%

Weight 122.8 lbs 100 140

Bioimpedance analysis of body composition involves indirect measurements. Only the impedance of the body itself, which is related to body composition, is measured directly. The rest of the analysis is complex and depends on body weight, height, gender, age, physique, and other individual parameters.

There is no completely accurate way to assess the body composition of a living person (in vivo). Nevertheless, several methods of determining body composition have been accepted by the scientific community as the gold standard:

- Dual-energy X-ray absorptiometry (DXA or DEXA)
- Hydrostatic underwater weighing (UWW)
- Deuterium oxide dilution
- Air displacement plethysmography (ADP)
- Determination of natural body radioactivity by potassium-40 isotope (40K)

Dual-energy X-ray absorptiometry (DEXA)

X-rays are partially absorbed by body tissues. The degree of absorption depends on the type of biological tissue, its thickness, and the energy of the radiation. If two radiation energies are used to measure the degree of absorption, both tissue type and thickness can be determined. This method can accurately determine the density of the skeletal bones, their mineral content, and the fat and fat-free mass of the body. It is probably the most common reference method for determining body composition.

Hydrostatic underwater weighing method

A person is placed in a tub of water. The volume of water displaced by the person is determined. The person is weighed in water and in the air. The density of the body is calculated according to Archimedes' principle, and then, using regression formulas, is recalculated in terms of fat and fat-free mass.

Air displacement plethysmography

A person is placed in a sealed chamber. His mass and the volume of air displaced by him is measured. The density of the body is calculated according to Archimedes' principle. Body density is recalculated into fat and fat-free mass using regression formulas.

Deuterium oxide (D2O) dilution method

Deuterium is a stable isotope of hydrogen with an atomic mass of 2. Deuterium oxide is used in various studies as a marker. To determine the total body water, the patient takes a precise amount of deuterium oxide. After a few hours, biological equilibrium is established: the concentration of deuterium oxide in the bodily fluids (blood, saliva, urine) is stabilized. Then, the concentration is measured. Knowing the mass of the injected marker and the mass of water in the liquid sample, you can calculate the total body water content.

Skinfold measurement

A special instrument, a caliper, is used to measure the thickness of the skin folds in certain parts of the body. For example, using the five folds method, measurements are taken above the biceps and triceps of the upper arm (in the middle between the acromial and ulnar processes), 2 cm from the lower angle of the scapula, above the crest of the iliac bone, and in the middle of the anterior surface of the thigh. There are several regression formulas that relate the thickness of the folds (usually the logarithm of their sum) and the percentage of fat.

Potassium-40 method

About 98% of potassium is found inside cells. In the human body, there is an unstable isotope of potassium called potassium-40 (40K).
The prevalence of this isotope is known. By measuring a person's natural radioactivity, it is possible to calculate the mass of potassium in the body. Based on the mass of potassium, the mass of cells containing it can be calculated.

Other methods

Other methods are also used to estimate body composition, for example:

- Anthropometric methods, most notably the US Navy method. Based on limb girth, neck circumference, height and weight, fat content is determined;
- Measuring the concentration of electrolytes in bodily fluids;
- Magnetic resonance imaging (MRI);
- Computed tomography (CT) scans.

Comparison of methods

No one method is universal. Each has its own limitations. For example, the DEXA method is considered the best method for determining bone density. However, it does not take into account the degree of hydration when estimating fat-free mass. Linear regressions embedded in the hydrostatic weighing and air plethysmography methods give near-perfect agreement with the other methods for people with normal body composition, but have significant discrepancies for people with severe deviations from the population norm.

Table 1. Comparison of body composition measurement methods

Method	Body parameter	Accuracy/ Repeatability, %	Cost	Availability
DEXA*	FM, FFM, BMC,	0.33 - 2	medium	high
D2O dilution*	TBW	1	high	low
Hydrostatic underwater weighing (UWW)*	FM, FFM	1.5	medium	low
Air displacement plethysmography (ADP)*	FM, FFM	1.5	high	low
Skinfold measurement	FM	1.5 - 5	low	high
Body radioactivity measurement*	CM, FFM	1.0	high	high

FM - fat mass, FFM - fat-free (lean) mass, BMC - bone mineral content, TBW - total body water, CM - cell mass

*gold standard

For methods accepted as «gold standard», it is impossible to unambiguously determine their accuracy. Typically, they are assigned a coefficient of variation (CV). There are also a number of cross-validation studies, where two or more methods are compared with each other. The reference methods are characterized by high levels of agreement (>0.95) between each other, despite the differences between the results.

Materials and methods

Participants

Forty-two healthy adults (21 male, 21 female, median age: 21.5, age range: 18-56) of Caucasian ethnicity participated in our study. They self-reported no recent history of hospitalization, alcohol or diuretic drug consumption. We had also set up initial exclusion criteria, which included chronic and acute conditions like diabetes mellitus, cancer, renal failure, hepatitis-related diseases, pregnancy, and presence of pacemakers or other electrical implantation. Our study was conducted in accordance with the Declaration of Helsinki recommendations: thus, participants were informed of the experimental purpose, methods, procedures, and safety-related information, and signed the informed consent before participation.

Experimental Procedure

Before the experiment, all participants were asked to fill out a questionnaire assessing their age, gender, physical training, habitual levels of smoking and alcohol consumption, recent intake of water and caffeine-containing products, normal sleep routine, medication, and menstrual cycle. After filling out the questionnaire, they were asked to take off any metal attachments such as jewelry and piercings, and change into cotton medical gowns. At the first step of our experiment, they took a Lunar iDXA body scan. After that, their total body mass (TBM) and height was assessed with a scale and stadiometer, respectively. Anthropometric measurements included hip and waist circumferences, as well as skinfold thickness at four sites (triceps, subscapular, suprailiac and mid-thigh) as described by Peterson and colleagues (Peterson M. et al. 2003. Development and validation of skinfold-thickness prediction equations with a 4-compartment model). Finally, body composition analyses were performed with inBody 230 and Samsung Galaxy Watch 4.

Bioimpedance Measurements

During the experiment, we placed the AURA Strap 2 (AS2) on participants' left wrist 2 cm below the lunate bone. The upper current and voltage electrodes of the AS2 came in contact with the central zone of the volar wrist. Hand-to-hand bioimpedance was then measured in a standing posture using a current frequency of 50 KHz. The positions of the AS2 electrodes are shown in Figure 1. Every measurement was replicated five times.

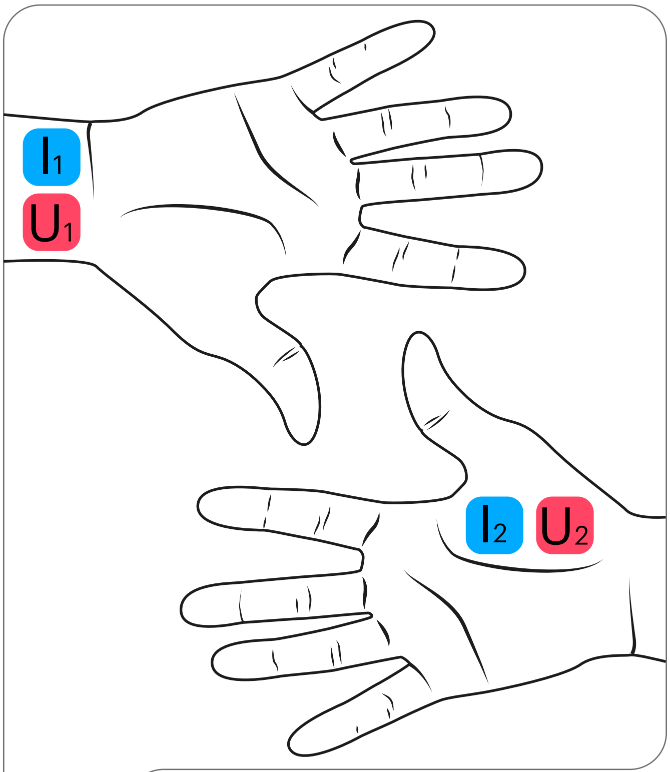


Figure 1 – Positions of AS2 electrodes on the left wrist and right hand during bioelectrical impedance measurement.

Statistical Analysis

We built linear regression models for FFM estimation using the least squares method. Height, age, TBM, sex, and BI (bioimpedance index, calculated as height2/R, where R denotes the real part of bioimpedance – resistance – between the voltage electrodes) were the independent variables, while fat free body mass, obtained by DEXA scan (FFMDXA) was the dependent variable. We used the bootstrap resampling method with 1,000,000 samples to derive regression coefficients, which virtually increased the amount of training data to make the model more robust. Coefficient of determination (r2), mean absolute percentage error (MAPE), and maximum residual error were the metrics of choice to evaluate both models' performance. In order to investigate the agreement between the FFM estimates provided by our model compared with InBody 230, the skinfold thickness based model, and Samsung Galaxy Watch 4 with the DEXA reference, we used Bland-Altman plots. A Bland-Altman plot consists of a plot of the difference between paired readings of two variables over the average of these readings, with ±1.96 standard deviation lines (called limits of agreement) parallel to the mean difference line.

Results

Anthropometry

The results of anthropometric measurements can be seen in Table 1. The mean (± STD, standard deviation) age of male and female participants was 24.95 ± 8.0 years and 29.1 ± 11.65 years, respectively. The physical condition of the participants was rather broad, from athletic to moderate obesity: The BMI and body fat percentages of the males were (23.69 ± 2.29) kg/m2 and (20.35 ± 7.55) % respectively, while the BMI and body fat percentages of the females were (23.51 ± 5.13) kg/m2 and (33.18 ± 5.9) % respectively.

	All (N=42)		**Male (n_{male} =21)**		**Female (n_{fem} =21)**	
	Mean value ± STD	**Value range**	**Mean value ± STD**	**Value range**	**Mean value ± STD**	**Value range**
Age, years	27.02 ± 10.2	18 - 56	24.95 ± 8.0	18 - 45	29.1 ± 11.65	18 - 56
TBM, kg	69.56 ± 11.29	45.83 - 100.95	74.75 ± 8.48	58.16 - 100.95	64.37 ± 11.36	45.83 - 98.15
Height, cm	171.89 ± 8.86	156.0 - 196.0	177.65 ± 6.85	168.4 - 196.0	166.14 ± 6.63	156.0 - 179.8
BMI, kg/m2	23.6 ± 3.97	18.17 - 38.87	23.69 ± 2.29	19.52 - 28.18	23.51 ± 5.13	18.17 - 38.87

Table 1. Anthropometry and body composition of study participants.

FFM estimation regression

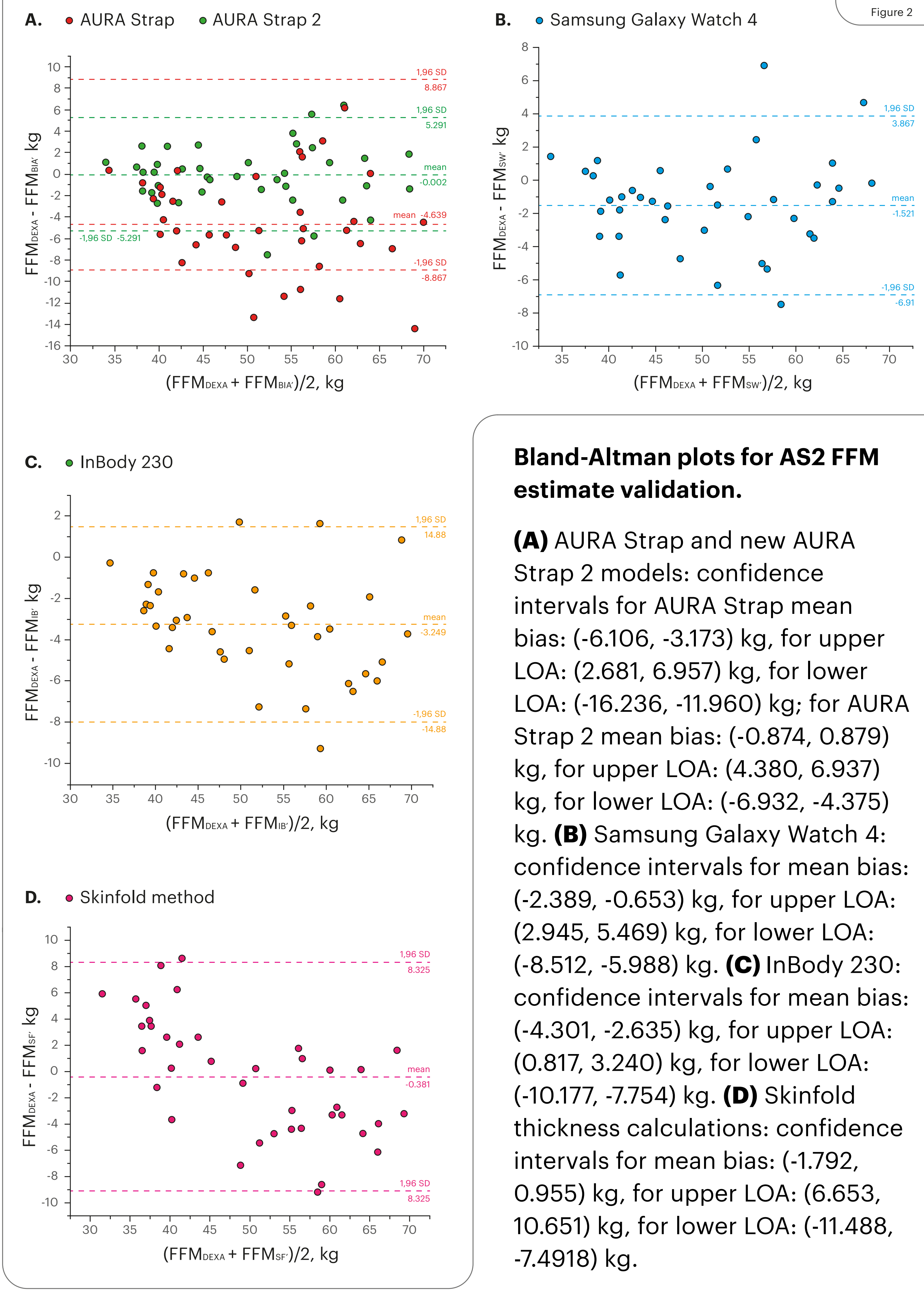
We built a linear regression model for estimating fat free mass, which demonstrated an r2 of 0.876 ± 0.054, an MAPE of 0.051 ± 0.009%, and a maximal absolute error of 8.623 ± 2.596 kg.

Bland-Altman plots

The Bland-Altman plots in Figure 2 demonstrate the agreement between our AURA Strap 2 model FFM estimation, the AURA Strap model, and the reference method (DEXA). Bland-Altman plots are usually interpreted as follows: a good agreement between methods demonstrated by smaller mean bias, whose confidence intervals include zero; for limits of agreement, the narrower the better, and it is necessary for them to include the zero line. As can be seen for AURA Strap 2 and DEXA, the mean bias between estimates was only 0.007 kg, which was not significantly different from zero, while the limits of agreement (LOA) were (-5.517; 5.517) kg, indicating very good accordance. These results are not surprising, considering the DEXA data was initially used to train the new model.

We also tested the original AURA Strap against the DEXA reference: the results are shown in Figure 2A in red. There are bigger mean differences between the methods, even though the zero line falls between the limits of agreement. Thus, the results demonstrate the improvement of body composition estimation accuracy for AURA Strap 2 compared with AURA Strap. Bland-Altman plots were also built for FFM estimates provided by other body composition assessment devices: Samsung Galaxy Watch 4 (Fig. 2, B) and inBody 230 (Fig. 2, C), as well as by an equation based on skinfold thickness measurements (Fig 2, D). Among these, the best agreement with reference values was reached by skinfold-based method calculations, with -0.381 kg mean bias; however its LOA – (-9.087; 8.325) kg – were the broadest ones.

Figure 2



Bland-Altman plots for AS2 FFM estimate validation.

(A) AURA Strap and new AURA Strap 2 models: confidence intervals for AURA Strap mean bias: (-6.106, -3.173) kg, for upper LOA: (2.681, 6.957) kg, for lower LOA: (-16.236, -11.960) kg; for AURA Strap 2 mean bias: (-0.874, 0.879) kg, for upper LOA: (4.380, 6.937) kg, for lower LOA: (-6.932, -4.375) kg. **(B)** Samsung Galaxy Watch 4: confidence intervals for mean bias: (-2.389, -0.653) kg, for upper LOA: (2.945, 5.469) kg, for lower LOA: (-8.512, -5.988) kg. **(C)** InBody 230: confidence intervals for mean bias: (-4.301, -2.635) kg, for upper LOA: (0.817, 3.240) kg, for lower LOA: (-10.177, -7.754) kg. **(D)** Skinfold thickness calculations: confidence intervals for mean bias: (-1.792, 0.955) kg, for upper LOA: (6.653, 10.651) kg, for lower LOA: (-11.488, -7.4918) kg.

Conclusion

A variety of methods are available for measuring and understanding human body composition. Among these methods is bioimpedance analysis: a safe, reliable and fast technique which employs predictive models based on the body’s electrical properties. By providing precise bioimpedance measurements and thoroughly validated models, AURA Strap 2 helps its users achieve their health goals. In this study, we aimed to ensure the accuracy of AURA Strap 2’s fat-free mass estimation by obtaining a range of parallel measurements made via our device and the reference method: DEXA. We then trained a novel predictive model, which demonstrated great performance in comparison with the original AURA Strap and other commercially available devices, such as inBody230 and Samsung Galaxy Watch 4, as well as other methods, such as skinfold thickness measurements. Thus, AURA Strap 2 provides accurate estimation of fat free mass using a wrist-wearable device, providing a convenient alternative to full-body BIA measurements, as well as other methods of body composition analysis.

Frequently Asked Questions

Why is body position important when measuring?

The blood supply to the upper body depends on whether the person is lying down, sitting or standing, and at what level their hands are relative to their heart. The impedance depends on the blood filling the upper part of the body. This difference does not exceed the average error in fat mass measurement. Our study validated measurements in the standing position with the hands at the level of the solar plexus. The user can also apply another pose. It is important that it is always the same. Otherwise, the spread of BIA results may increase.

Why is it important to take measurements at the same time of day?

The composition of the human body is subject to cyclic fluctuations. For example, daily (circadian) variations in total body water have a value of about 1 kg. In case of heart or kidney diseases, there may be swelling in the morning. We recommend taking measurements in the evening before meals.

Why is it important that the skin of the hands is clean and dry when measuring?

Excessive moisture on the skin (such as sweat) can cause electrical leakage between the electrodes and errors in body impedance measurements. Skin impurities can prevent the normal flow of current through the body and can also lead to errors. Skin defects, wrist and thenar injuries can lead to errors for the same reason.

I’m following all the recommendations, but I have a wide range of BIA results. Why is this happening?

There are several factors that can complicate the measurement process. Proper measurements must be taken in a hand position that may be unusual for most users. The dimensions of the Strap 2 are quite small. During the measurement, the place of contact between the electrodes and the skin is not visible. For these reasons, the user’s hands may be touching each other or not fully touching the electrodes. If the hands touch each other during the measurement, part of the electric current does not flow through the body, but through the place of contact.
In practice, this leads to an abnormally low fat mass value measurement. If the hands do not touch the entire surface area of the electrodes, there may be an error measuring body impedance. This error can lead to either an overestimated or underestimated fat mass.

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About AURA Devices

AURA Devices was founded in May 2016 by a team of passionate enthusiasts with a goal to bring true innovation into the wearables field. We are a global team of qualified engineers and creatives located on every continent – with a dream to make people healthier and mindful about the performance of their bodies.

Our first product was the AURA Band, a fitness-tracker with body composition analysis, that was successfully funded on Kickstarter. It could tell what you're made of using the progressive technology of bioelectrical impedance.

AURA Strap – our next key invention – was launched in 2019 as a unique accessory for Apple Watch, that allowed tracking body composition while utilizing the most convenient form factor.

All our tech is developed in association with reputable public research universities, such as the University of Jaén in Spain, the University of Alabama in the United States, and the University of Alberta in Canada. Scientific articles from our R&D team get featured in renowned natural science journals such as Nature's Scientific Reports.

Since 2016 we have sold over 20000 units of AURA bands and straps. Our products have been featured in Engadget, iMore, Wareable, and Entrepreneur, and we received awards from CES and Indiegogo.

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